IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

	PROFES PROFES OF CUIDICAL IDEA (NO DUE D	
Customer No.	022913	<u> </u>
Examiner:	M.D. Burkhart	<u> </u>
Filing Date:	February 5, 2002	<u> </u>
For:	A METHOD FOR EXTRACTING QUANTITATIVE INFORMATION RELATING TO AN INFLUENCE ON A CELLULAR RESPONSE)))
Confirmation No.	3012	<u> </u>
Serial No.	10/072,036) 1633
	Ole Thastrup et al.))) Art Uni
In application of:)

DECLARATION OF CHRIS M. IRELAND. PH.D. UNDER 37 C.F.R. & 1.132

Mail Stop AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

- I. Chris M. Ireland, Ph.D., hereby declare as follows:
- 1. I am personally knowledgeable of the facts stated herein.
- 2. I am a professor and chairman of the Department of Medicinal Chemistry in the College of Pharmacy at the University of Utah, Salt Lake City, Utah. I have significant experience in preparing compounds and screening compounds for biological activity (see Appendix A: Curriculum Vitae of Chris M. Ireland). Additionally, I am knowledgeable in the field of developing and validating high throughput screening (HTS) assays for biological activity and drug development, and also knowledgeable in the field of formatting and processing of chemical diversity libraries for use in HTS assays. I am therefore knowledgeable in the field preparing and screening compounds for biological activity, such as disclosed and claimed in the U.S. Patent Application Serial No.10/072,036 ("Subject Application"), which is currently under examination.

- 3. I have reviewed and understand the Subject Application and the *Carey* reference cited by the Examiner in the Office Action of October 20, 2006.
- I am not an inventor of the subject matter disclosed and claimed in the Subject Application.
- I am not currently employed by and have never been employed or associated with Fisher BioImage ApS or Thermo Fisher Scientific.
 - 6. I do not have a personal interest in the Subject Application.
- 7. A dictionary definition of "library" reads as follows: "[a] place in which literary and artistic materials, such as books, periodicals, newspapers, pamphlets, prints, records, and tapes, are kept for reading, reference, or lending"; "[a] collection of such materials, especially when systematically arranged"; "[a] room in a private home for such a collection"; "[a]n institution or foundation maintaining such a collection"; "[a] commercial establishment that lends books for a fee"; "[a] series or set of books issued by a publisher"; "[a] collection of recorded data or tapes arranged for case of use"; "[a] set of things similar to a library in appearance, function, or organization: a library of computer programs"; and "Genetics A collection of cloned DNA sequences whose location and identity can be established by mapping the genome of a particular organism." (See, The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. 21 Feb. 2007. <Dictionary.com http://dictionary.reference.com/browse/library>.)
- 8. A dictionary definition of "compounds" with respect to the field of chemistry reads as follows: "[a] pure, macroscopically homogeneous substance consisting of atoms or ions of two or more different elements in definite proportions that cannot be separated by physical means. A compound usually has properties unlike those of its constituent elements." (See, *The American Heritage* ® *Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. 23 Feb. 2007. <Dictionary.com http://dictionary.reference.com/browse/compound>.)
- 9. The ordinary meaning of a "library of compounds," as evidenced by the aforementioned dictionary definitions, is a collection of compounds that are either pure or present at a known concentration, and such compounds of the library of compounds are arranged for ease of use. Additionally, the plain meaning of a "library of compounds" is similar to a standard book library in appearance, function, or organization.
- 10. As used in the Subject Application, a "library of compounds" is a term of art that is well known to those of ordinary skill in the art of screening compounds. A skilled artisan in the art of screening compounds would understand a "library of compounds" to be a collection of compounds that

are either pure or present at a known concentration, and arranged so that each compound can be selected from the collection of compounds for use in an experiment either alone or in combination with other compounds of the library. Also, a skilled artisan would understand that a library of compounds is a collection of compounds assembled for the purpose of testing the compounds to determine suitability for a particular purpose, or to detect wanted or unwanted attributes of the compounds. Additionally, a skilled artisan would understand that a "library of compounds" has a function similar to a standard book library in that each compound of the collection of compounds is individually retained within a container such that a single compound of the collection of compounds can be individually selected for use similar to how a single book can be selected in a standard book library. The compounds can be individually retained in the container in a pure state or in a specific, known concentration in a specific solvent that is compatible with the environment in which the compound will be used, wherein the container is substantially devoid of any contaminating compounds or substances. Furthermore, a skilled artisan would understand that more than one compound of a "library of compounds" can be selected as a group for use similarly to how a group of books can be selected in a standard book library.

- 11. A dictionary definition of "screening" reads as follows: "[t]o examine (a job applicant, for example) systematically in order to determine suitability"; "[t]o test or evaluate (a student) to determine placement in an educational system or to identify specific learning needs"; "[t]o test or examine for the presence of disease or infection: screen blood; screen a patient"; "[t]o subject to genetic screening"; and "[a] systematic examination or assessment, done especially to detect an unwanted substance or attribute. (See, The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. 23 Feb. 2007. <Dictionary. com http://dictionary.reference.com/browse/screening≥.)
- 12. The ordinary meaning of "screening a library of compounds," as evidenced by the aforementioned dictionary definitions, is a process to systematically examine, test, or evaluate the compounds or a combination of compounds of a library of compounds to determine suitability for a particular purpose, or detect wanted or unwanted attributes of the compound.
- 13. As used in the Subject Application, "screening a library of compounds" is a term of art for an experimental process that is well known to those of ordinary skill in the art of screening compounds. A skilled artisan in the art of screening compounds would understand "screening a library of compounds" to be a process to systematically examine, test, or evaluate the compounds of the library of compounds in order to determine suitability for a particular purpose, or to detect wanted or

unwanted attributes of the compounds. Additionally, a skilled artisan in the art of screening compounds would understand that "screening a library of compounds" would include a process to systematically examine, test, or evaluate whether or not a known concentration of a compound or a combination of compounds of the library of compounds is biologically active, and so that the biological activity can be correctly attributed to a known concentration of the compound. Furthermore, such "screening a library of compounds" inherently includes comparing a compound or a combination of compounds of the library of compounds to a control so that the presence or absence of any biological activity is correctly attributed to the compound or combination of compounds.

- 14. The specification of the Subject Application (PG-PUB 2003/0082564) discloses a "library of compounds" at the following paragraphs: [0027] and [0103]. Additionally, the specification of the Subject Application (PG-PUB 2003/0082564) discloses a "screening" at paragraphs [0001], [0013], [0027], [0036], [0058-0063], and [0126-0141]. The Examples and Figures describe protocols and illustrate results for such a screening. Thus, the Subject Application discloses "screening a library of components."
- 15. The Carey reference does not disclose a "library of compounds" or a group of compounds that could be construed as a "library of compounds" because there is no reference to a collection of compounds that are each either pure or present at a known concentration, and that are assembled for the purpose of testing the compounds to determine suitability for a particular purpose, or to detect wanted or unwanted attributes of the compounds.
- 16. A skilled artisan would not consider "any and all substances [or compounds] mentioned in the Materials and Methods section on pages 986-987" in the Carey reference to be a library of compounds. In part, this is because the substances of Carey are not described to have each compound of the substance to be individually retained within a container at a known concentration such that a single compound of the substance can be individually selected. Additionally, the Materials and Methods section of Carey does not teach or suggest the compounds recited therein are a "library of compounds" that are assembled for the purpose of testing the compounds to determine suitability for a particular purpose, or to detect wanted or unwanted attributes of the compounds.
- 17. A skilled artisan would not consider dexamethasone, phenol red, serum, and charcoal-stripped serum to be a library of compounds because only dexamethasone could be construed to be a compound that is either pure or present at a known concentration. Also, Carey does not teach or suggest that phenol red is available for being selected in the absence of cell culture media, and thereby phenol red is not taught or suggested to be present in a pure state or in a specific, known concentration

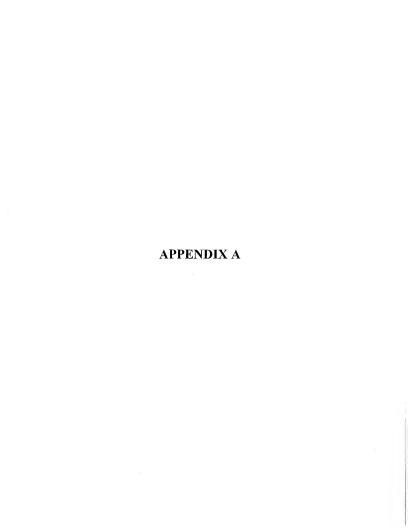
in a specific solvent that is compatible with the environment in which the compound will be used, wherein the solvent is substantially devoid of any contaminating compounds or substances because the other compounds contained in media would be considered to be contaminants. Additionally, neither serum nor charcoal-stripped serum is a pure compound, and the compounds contained therein are not all present at known concentrations.

- 18. A skilled artisan would not consider the compounds contained in serum or charcoal-stripped serum to be a library of compounds because the compounds contained therein are not pure and are not all present at known concentrations because serum contains many compounds at unknown concentrations. Also, the compounds of serum are not a collection of compounds that are individually retained within a container such that a single compound can be individually selected.
- 19. The Carey reference does not disclose a method of "screening a library of compounds," or reference any experiment (e.g., experiments conducted with dexamethasone, phenol red, serum, and/or charcoal-stripped serum) that a skilled artisan would construe as "screening a library of compounds" because a "library of compounds" is not taught or suggested as discussed above. Additionally, only dexamethasone could be construed to be in a pure state or at a known concentration that is included in a process to be systematically tested to determine suitability for a particular purpose, or to detect wanted or unwanted attributes, and testing dexamethasone alone does not constitute "screening a library of compounds."
- 20. I declare further that all statements made herein of my own knowledge are true and that all statements are made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 2014 day of March, 2007.

CHRIS M. IRELAND, Ph.I



CURRICULUM VITAE

CHRIS M. IRELAND

University of Utah College of Pharmacy Department of Medicinal Chemistry Salt Lake City, Utah 84112 (801) 581-8305

Birth date

November 22, 1951, San Diego, California, U.S. Citizen

Marital Status

Married, four children

Education

Position

1973

1977

1983-86

	,	
Professional/Resea 2002-	rch Experience Chair, Department of Medicinal Chemistry	
1991-	Adjunct Professor, Department of Chemistry, University of Utah	
1991-	Professor, Department of Medicinal Chemistry, College of Pharmacy, University of Utah	
1986-91	Adjunct Associate Professor, Department of Chemistry, University of Utah	
1986-91	Associate Professor, Department of Medicinal Chemistry, College of Pharmacy, University of Utah	

Professor and Chair, Department of Medicinal Chemistry

B.A. University of California, San Diego

Ph.D. Scripps Institution of Oceanography

APPENDIX A

Adjunct Assistant Professor, Department of Chemistry, University of Utah

1983-86 1980-83	Assistant Professor, Department of Medicinal Chemistry, College of Pharmacy, University of Utah Assistant Professor, University of Connecticut
1980	Postdoctoral Fellow, University of Illinois
1978-80	NIH Postdoctoral Fellow, University of Hawaii

Professional/Research Interests

Marine pharmacognosy, natural products chemistry, structure and mechanism of action of antitumor natural products, marine microbiology, structure and neurotoxicity of conotoxins

Scientific/Professional Societies

American Chemical Society-Organic Division American Society of Pharmacognosy American Association of Cancer Researchers

Honors and Distinctions

2	2007	University of Utah, Distinguished Scholarly & Creative Research Award
2	2006	University of Utah, Distinguished Graduate Research Mentor Award
2	2006	College of Pharmacy, University of Utah, Distinguished Teaching Award
1	987-92	National Institutes of Health Research Career Development Award
1	985-89	Alfred P. Sloan Foundation Fellow
1	.981	University of Connecticut Summer Faculty Fellow
1	978-80	National Institutes of Health Postdoctoral Fellow

National Public Service Activities and Committee Memberships

American Society of Pharmacognosy, Chairman, Awards and Funds Committee, 1985-88
American Society of Pharmacognosy, Chairman & Host, 1988 Annual Meeting
Member Bio-organic and Natural Products study section-NIH, 1989-1993
Vice-President/President Elect, American Society of Pharmacognosy, 1990-91
Co-Chairman, Marine Natural Products Gordon Conference, 1990
President, American Society of Pharmacognosy, 1991-1992
Chairman, Marine Natural Products Gordon Conference, 1992
American Society of Pharmacognosy, Chair, Scientific Committee & Member, Local
Committee, 1993 Annual Meeting
American Society of Pharmacognosy, Chair, Personnel Committee, 1993-1996

APPENDIX A

NIH DRG Reviewers Reserve, 1993- Have served ad hoc on numerous study sections and site visit teams

American Society of Pharmacognosy, Chair, Research Achievement Award Committee,

American Society of Pharmacognosy, Chair, Honorary Membership Committee, 2001-2004

Journal Review Activities:

Tetrahedron Letters

Journal of the American Chemical Society

Journal of Organic Chemistry

Journal of Natural Products

Tetrahedron

Journal of Medicinal Chemistry

Marine Drugs

Organic Letters

Editorial Board Membership

Journal of Natural Products

1999-present Philippine Journal of Science 1999-present

Marine Drugs 2002-present

Consultant/Advisory Positions (past and present)

Member, Scientific Advisory Board, Mycosynthetix, Inc.

Member, Scientific Advisory Board, INI Health

Member, Scientific Advisory Board, OSI Pharmaceuticals Member, Scientific Advisory Board, NPS Pharmaceuticals

Member, Scientific Advisory Board, Ancile Pharmaceuticals

University Service Activities and Committee Memberships

Combined Programs in Biological Chemistry and Molecular Biology, Executive

Committee (University)

Incentive Seed Grants Program (University)

Curriculum Committee (College)

Computer Advisory Committee (College)

Instrument Room Committee (College)

Scholastic Standards Committee (College)

Awards and Funds Committee (College)

Chair of Search Committee for Chairperson of the Department of Pharmacology and

Toxicology (College)

NMR Committee (Department)

Department Teaching Committee (Department)

Biological Chemistry Program steering committee (University) College of Pharmacy Executive Committee (College)

University Teaching/Advisory Committees

Courses taught/new courses developed

PHARM SCI 410 Basics in Pharmaceutical Sciences Basics in Pharmaceutical Sciences PHARM SCI 411 PHARM SCI 5113 Basics in Pharmaceutical Sciences MED CHEM 556 Physiological Chemistry MED CHEM 561 Natural Products MED CHEM 601 Instrumental Methods MED CHEM 789 Seminars MED CHEM 652 Natural Product(Grad)

Research Faculty Supervised

Rohan Davis, Ph.D., Research Assistant Professor Timothy S. Bugni, Ph.D., Research Assistant Professor

Post Doctoral Students Supervised-Current Position

Deborah M. Roll, Ph.D.-Senior Scientist, Wyeth Averst Research

Tadeusz F. Molinski, Ph.D.-Professor, Department of Chemistry, UC-San Diego Bradley S. Davidson, Ph.D.-Associate Professor, Department of Chemistry, Utah State University

Robert R. West, Ph.D.-Senior Scientist, Zymogenetics

Brent D. Copp, Ph.D.-Senior Lecturer, Department of Chemistry, University of Auckland

Jodi A. Laakso, Ph.D.-Research Scientist, New Chemical Entities, Inc.

Tommaso A. Foderaro, Ph.D.-Research Scientist, Ciba Gigy

Todd L. Capson, Ph.D.-Research Assistant Professor, Department of Biology, University of Utah

Debra Venables, Ph.D.-Research Scientist, AstraZeneca-Griffith Univeristy

Cameron J. Smith, Ph.D.-Senior Scientist, Merck

Deniz Tasdemir, Ph.D.- Lecturer, University of London

Rohan Davis, Ph.D. - Assistant Lecturer, Griffith University

Damian Laird, Ph.D. - Research Associate, Murdoch University

Camille Chevalier, Ph.D. - Present

Anokha Ratnayake, Ph.D. - Senior Scientist, Wyeth

Daniel LaBarbera, Ph.D. - Present

Kaleem Mohammad, Ph.D. - Present

Rachel Jadulco, Ph.D. - Present

Malcolm McCulloch

Students Graduated

Joseph E. Biskupiak, Ph.D., Associate Professor of Pharmacy Practice, University of Utah

David F. Sesin, Ph.D. - Senior Scientist, Shaman Pharmaceuticals T. Mark Zabriskie, Ph.D. - Associate Professor, College of Pharmacy, Oregon State University

Tawnya C. McKee, Ph.D. - Staff Research Fellow, National Cancer Institute Mark P. Foster, Ph.D. - Associate Professor, Department of Biochemistry, Ohio State University

Leonard A. McDonald, Ph.D. - Research Scientist, Wyeth Ayerst Research

J. Christopher Swersey, M.S. - Brewmaster

Annette M. Fernandez, Ph.D. - Bristol Myers Squibb

Scott S. Mitchell, Ph.D. -Senior Scientist, Nereus Pharmaceuticals Ryan VanWagoner, Ph.D. - Research Assistant Professor, UNC-Wilmington

Robyn James, M.S. - Research Associate, Birnham Institute
Adam Richardson, Ph.D. - Postdoctoral Fellow, Birnham Institute

Tim Bugni, Ph.D. - Research Assistant Professor, University of Utah Sheryl Verbitski, Ph.D. - Senior Scientist, ChromaDex

Imelda Sandoval, Ph.D. - Postdoctoral Fellow, Huntsman Cancer Institute

Current Graduate Students Supervised

Emily Whitson (4rd year) Charles Veltri (4rd year)

Visiting Scholars Supervised

Imelda Sandoval- University of the Philippines Giselle Concepcion - University of the Philippines Teatulohi Matianaho - University of Papua New Guinea Brent Copp - Auckland University Manah Dindi - University of Papua New Guinea

Grant Awards History (Current awards are in italics)

NIH Grant 1 S15 CA46245-01; "Silicon Graphics Iris 3130 Work Station," September 30, 1987 to September 29, 1988, \$22,888

College of Pharmacy - BRSG; "Cultured Blue-Green Algae" Sept. 1, 1985 to August 30, 1986, \$3,500

Alfred P. Sloan Foundation; September 16, 1985 to September 16, 1987, \$25,000

University of Utah Research Committee; "Antiviral Agents from Marine Organisms" November 1, 1983 to October 21, 1984, \$5,000

NIH Grant CA29821; "Antineoplastic Agents from Marine Organisms" May 1, 1982 to August 31, 1983, \$86,449

PRF Grant 12730-G4; "Photosynthetic Molluscs" September 1, 1980 to August 31, 1982, \$10,000

UCRF Grant 35-420; "Marine Molluscs" September 1, 1980 to August 31, 1981, \$9,490

NIH Grant CA01179; RCDA April 1, 1987 to March 31, 1992, \$256,000 (direct costs)

NIH Grant CA50750; "National Cooperative Natural Product Drug Discovery Group" September 1, 1989 to June 30, 1994, Co-Investigator, total budget \$2,500,000

NIH Grant S10 RR06262; "500 MHZ NMR Spectrometer" July 18, 1991 to July 17, 1992 \$400,000 (total costs)

California Sea Grant College Grant S145-N-N; "Technology for Discovery of Anti-Cancer Drugs from Marine Sources" October 1, 1995 to September 30, 1998, Co-Investigator, \$195,793 (total costs)

DOC, NOAA Grant NA36RG0036; "Metabolite Studies with Marine Microorganisms" July 1, 1996 to June 30, 1999, \$310,000.

NIH Grant "Varian INOVA 600 MHZ NMR Spectrometer" April 1, 1999, to March 31, 2000, \$470,732 (total costs).

NIH Grant CA67786; "Anticancer Agents from Unique Natural Products Sources" September 8, 1995 to August 31, 2000, \$2,348,308 (total costs).

NIH Grant CA67786; "Anticancer Agents from Unique Natural Products Sources" September 8, 2000 to August 31, 2005, \$4,360,000 (total costs).

Fogarty - FIRCA R03TW06008-01, HIV and TB Screening of PNG Marine Organisms 08/15/2002 - 07/31/2005, \$90,000 total costs.

NIH Grant CA36622-19-24 "Antineoplastic Agents From Marine Organisms" June 1, 2001 to May 31, 2006, \$1,150,000 (direct costs).

American Cancer Society RSG-02-141-01-CNE (David Jones, PI) Retinoid Biosynthesis in Colon Tumorgenesis 07/02/02 – 06/30/06.

ICBG - Fogerty Foundation Conservation and Sustainable Use of Biodiversity of Papua New Guinea (Chris M. Ireland and Louis R. Barrows, co-PIs) 09/01/03 - 8/31/08, \$3,500,000 total costs, 09/25/03 - 05/31/08.

NIII Grant CA67786, 11-15; "Anticancer Agents from Unique Natural Products Sources" September 26, 2005 to April 30, 2010, \$5,920,782 (total costs).

NIH Grant CA36622-24-28 "Antineoplastic Agents From Marine Organisms" December 1, 2006 to November 31, 2011, \$1,250,000 (direct costs).

Publications

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- Ramenofsky, M.; Faulkner, D.J.; Ireland, C. Effect of Juvenile Hormone on Cirriped Metamorphosis Biochem. Biophys. Res. Comm. (1974) 60, 172-178.
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- Zabriskie, T.M. and Ireland, C.M. The Isolation and Structure of Modified, Bioactive Nucleosides from *Jaspis johnstoni J. Nat. Prod.* (1989) 52, 1353-1356.
- Molinski, T.F.; Ireland, C.M. Varamines A and B, New Cytotoxic Thioalkaloids from Lissoclinum vareau J. Org. Chem. (1989) 54, 4256-4259.
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